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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/446,379	02/11/00	THOMSON	B PUE597050/MP

000881
LARSON & TAYLOR, PLC
1199 NORTH FAIRFAX STREET
SUITE 900
ALEXANDRIA VA 22314

HM11/0622

EXAMINER
OZGA, B

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 06/22/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Offic Action Summary	Application No.	Applicant(s)
	09/446,379	THOMSON ET AL.
Examiner	Art Unit	
Brett T Ozga	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-19 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-19 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) Notice of References Cited (PTO-892)
- 16) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 18) Interview Summary (PTO-413) Paper No(s) _____.
- 19) Notice of Informal Patent Application (PTO-152)
- 20) Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless —

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-6, 13 and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Cahn (WO 97 06837).

The instant application claims a wound dressing comprising a carrier layer (polymeric material) having a wound-facing surface, said surface being non-adherent to anchorage-dependent cells and having disposed thereon a biodegradable cell anchoring layer containing fibroblasts. Dependent claims further limit by adding a material adherent to anchorage-dependent cells. It also claims a method of treating a skin trauma site on a mammalian patient comprising the step of applying to a patient a wound dressing.

Cahn teaches a wound dressing comprising crosslinked-glycosaminoglycan composite having a wound-facing surface, said surface being non-adherent to anchorage-dependent cells and having disposed thereon a biodegradable cell anchoring layer. (See p. 1, lines 12-24) Cahn also teaches a method of treating a skin trauma site on a mammalian patient comprising the step of applying to a patient a wound dressing. (See abstract, claims 1 and 2) Cahn teaches fibroblasts. (p.2, line 20) Cahn teaches the adherent material comprising a polymer selected from polyurethanes and the wound-facing surface treated with silicone. (See p. 12-13)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cahn in view of Richardson et al. (WO 97/06835) and Soon-Shiong et al. (WO 93/09176).

The instant application claims a wound dressing comprising a cross-linked hydroxyalkyl cellulose, a cross-linked carboxyalkyl cellulose, a polyvinyl alcohol or an agarose having a wound-facing surface, said surface being non-adherent to anchorage-dependent cells and having disposed thereon a biodegradable cell anchoring layer.

Cahn teaches a wound dressing comprising crosslinked-glycosaminoglycan composite having a wound-facing surface, said surface being non-adherent to anchorage-dependent cells and having disposed thereon a biodegradable cell anchoring layer. Cahn teaches fibroblasts. (p.2, line 20)

Cahn does not teach the cell anchoring layer having anchored thereto mammalian cells which form a cell layer. Cahn does not teach keratinocytes. Cahn does not teach a wound dressing wherein the cell layer comprises both autologous and allogenic cells. Cahn does not teach a cell culture system comprising a vessel having interior and exterior surfaces for containing a liquid culture medium for culturing cells and the dressing. Cahn also does not teach a method of preparing a wound dressing.

Richardson et al. teach the cell anchoring layer having anchored thereto mammalian cells which form a cell layer. (See abstract.) Richardson et al. teach keratinocytes and cell layer of autologous and allogenic cells. (See p. 11) Richardson et al. teach a cell culture system comprising a vessel having interior and exterior surfaces for containing a liquid culture medium for culturing cells and the dressing as well as a method of preparing a wound dressing. (See p. 12)

Cahn also does not teach the wound dressing wherein the polyanion is a heparin or the wound dressing wherein the biodegradable cell anchoring layer is polylysine.

Soon-Shiong et al. teach the wound dressing wherein the polyanion is a heparin or the wound dressing wherein the biodegradable cell anchoring layer comprises polylysine. (p. 11 and 12)

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to modify the wound dressing of Cahn by the addition of heparin and polylysine of Soon-Shiong et al. to obtain the known and disclosed advantage as disclosed by Soon-Shiong et al. as being the most biocompatible polyanion and biodegradable cell anchoring layer. Thus, in view of the cited references, the artisan of ordinary skill would have been motivated to have practiced the invention as recited in the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brett T Ozga whose telephone number is 7033050634. The examiner can normally be reached on M-F 0530-1500, 2nd Wednesday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 7033084743. The fax phone numbers for the organization where this application or proceeding is assigned are 7033084242 for regular communications and 7033053014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 7033080196.



FRANCISCO PRATS
PRIMARY EXAMINER